



UNITED STATES PATENT AND TRADEMARK OFFICE

107

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,392	07/23/2003	Stefan Assmann	P03,0017	9086

7590 09/05/2006
SCHIFF HARDIN & WAITE
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, IL 60606

EXAMINER

SOLANKI, PARIKHA

ART UNIT PAPER NUMBER

3737

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,392

Applicant(s)

ASSMANN ET AL.

Examiner

Parikha Solanki

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/23/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claims 1-16, the abstract idea of classifying plaque is not practically applied. It is suggested that claim 1 be modified to include a step describing what is done following plaque classification, i.e. prescription of further treatment based on the type of plaque classified. These claims have been examined in accordance with the "Interim Guidelines" for patent subject matter eligibility (see 1300 OG 142, 22 November 2005).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim includes the phrase "said computer," which is considered vague and indefinite due to the citation of multiple computers in the parent claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3737

6. Claims 1, 3-5, 7, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Prince ('767).

Regarding claims 1, 7, 15 and 16, Prince ('767) discloses a method of arterial MR imaging which may be used to for detecting, examining and grading occlusive lesions, which are equivalent to arterial plaque or atheroma (col. 5 line 62). Prince ('767) discloses that the method comprises the steps of collecting an initial baseline MR image (col. 5 line 33), injecting a gadolinium-based contrast agent such as Gd-DTPA into the subject (Figs. 1 & 5A), and collecting several contrast-enhanced MR images following injection (col. 5 line 43). The MRI scanner disclosed by Prince ('767), a 1.5T GE Signa v4.7, is inherently capable of collecting data via FLASH sequences (col. 13, line 3). Prince ('767) further discloses determining the intensity distribution over time from the images from the selected region (Fig. 9)

Regarding claims 3 and 4, Prince ('767) teaches the collection of image data at the time of elevated arterial contrast, equivalent to the enrichment phase (col. 6 line 53). Prince ('767) teaches that such a time occurs between 10 and 50 seconds post-infusion, equivalent to approximately one minute following injection of the contrast agent (col. 8 line 29).

Regarding claims 5 and 6, Prince ('767) discloses the collection of image data post-infusion and following the time of elevated contrast absorption, which is equivalent to the flushing phase as described by the applicant (col. 4 line 59, Fig. 9). Prince ('767) shows that, for three patients, the flushing phase occurs at approximately 3 minutes post-infusion in the aorta and IVC (Fig. 9), and it is obvious that the flushing phase for the rest of the vascular system occurs in the same time frame as for these two anatomical regions.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 2 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince ('767) in view of Cai (2002).

Regarding claim 2, Prince ('767) teaches all limitations of claim 1 as described above. Prince ('767) is silent with respect to the method of classifying plaque. Cai (2002) teaches that

Art Unit: 3737

plaque may be classified according to composition, which is well known in the art to be a direct indicator of propensity for dislodgement, also known as vulnerability (p. 1369, Table 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Prince ('767) by adding the step of classifying plaque according to composition as a direct indicator of vulnerability, in light of the teachings of Cai (2002).

Regarding claims 9-14, Prince ('767) teaches all limitations of claim 1 as described above. Prince ('767) is silent with respect to the basis of plaque classification. Cai (2002) discloses plaque classes including plaque composed of lipid content, thrombus, fibrotic content, and calcification (p. 1369, Table 1). It is known in the art that small blood vessels may form around arterial plaque and thereby contribute to its vulnerability, and as such it would have been obvious to one of ordinary skill in the art to classify plaque by the presence of such angiogenic growth in view of the method disclosed by Cai (2002). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Prince ('767) by further classifying plaque in different groups based upon the presence of deposits, small vessel formation, inflammation, fibrotic content, and/or calcification in order to better predict risk of vulnerability, in light of the teachings of Cai (2002).

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Prince ('767) in view of Clarke (2000). Prince ('767) discloses a method for classifying plaque in a blood vessel as described above. Prince ('767) does not disclose defining a line in the series of MR images and determining the respective intensity distributions along those lines. Clarke (2000) teaches the use of a maximum likelihood classification algorithm, which evaluates signal intensity on a pixel by pixel basis across a series of images (p. 306, Fig. 1), in order to provide for an automated method of analyzing MR images for plaque to reduce operator error. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Prince ('767) by adding a pixel-by-pixel analysis algorithm, which inherently creates intensity lines, to more accurately classify plaque, in light of the teachings of Clarke (2000).

10. Claims 17-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prince ('767) in view of Clarke (2000).

Regarding claims 17-33, Prince ('767) discloses an apparatus that meets all limitations of these claims, with the exception of a diagnostic computer supplied with data from the system

Art Unit: 3737

computer for calculating signal intensities and classifying plaque in a plurality of classes including those representing composed of fat deposits, inflammations, fibrous tissue, or calcifications (Figs. 1 & 5A, col. 17 line 31, col. 6 line 53, col. 8 line 29, col. 4 line 59, Fig. 9). Clarke (2000) discloses an algorithm for classifying plaque based on composition, which is known in the art to be a direct indicator of propensity for dislodgement (p. 306). It is obvious that a computer algorithm inherently must be used with a computer. The algorithm of Clarke (2000) employs multispectral analysis to assess the material present in the region. It is well known that spectral analysis and intensity distribution both quantify the amount of a specific type of material present in an image. The algorithm of Clarke (2000) calculates signal intensity on a pixel by pixel basis, in which the pixels can inherently create lines, and further analyzes the intensities across a series of images of the same region, motivated by the need to minimize operator error via image processing automation (Fig. 1). Furthermore, the computer of Clarke (2000) classifies plaque according to presence of fibrous plaque, calcification, cholesterol, fibrin, cellular plaque and intraluminal thrombus (p. 306 ¶2), and the obviousness of including a class for small vessel formation in view of the method of Cai (2002) has been previously addressed here. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the apparatus of Prince ('767) with the diagnostic computer and algorithm of Clarke (2000) to easily and accurately classify plaque composition and vulnerability.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Choudhury (2002) and Mofidi (2001) clearly demonstrate that it is known in the art that small vessel angiogenesis is a risk factor for plaque vulnerability.

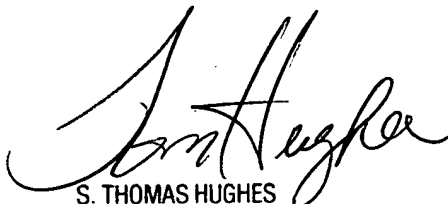
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PS
Parikha Solanki
30 August 2006



S. THOMAS HUGHES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700